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I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2003/0585
Date of Filing	7 August 2003
Applicant	BRIVANT RESEARCH & DEVELOPMENT LIMITED, an Irish Company of Unit 6, Campus Innovation Center, Newcastle Road, Galway, Ireland.

Dated this 17 day of August 2004.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S U 3 U 5 8 5

FORM NO. 1 Application No. _____

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

[ ] the grant of a patent under Part II of the Act

[X] the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

BRIVANT RESEARCH & DEVELOPMENT LIMITED

Address

Unit 6, Campus Innovation Center, Newcastle Road, Galway, Ireland.

Description/Nationality

An Irish company.

2. Title of Invention

"A guide wire for use with a catheter"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

HENRY WILLIAM LUPTON

Address

Minehill House, Renville West, Oranmore, County Galway, Ireland; an Irish citizen.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**
The applicant has derived the right to be granted a Patent from the inventor by virtue of a Deed of Assignment dated July 28. 2003

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€ 60.00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [ ] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**
The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....

8. **Agent**
The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**
F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed

BRIVANT RESEARCH & DEVELOPMENT LIMITED

BY: _____

CAPACITY: Managing Director

Oifig na bPaitinn
FAIGHTE
7 AUG 2003

Date July 28. 2003

"A guide wire for use with a catheter"

The present invention relates to a guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, and in particular though not limited to a guide wire for use with a catheter. The invention also relates to a method for producing a guide wire.

Guide wires for locating a distal end of a catheter in a remote site in the body of a human or animal subject are known. Such guide wires are commonly used for guiding a catheter along narrow blood vessels to a site in the cardiovascular system of the subject for enabling cardiovascular procedures to be carried out. Typically, the guide wire is introduced through a cannula into a suitable blood vessel in the thigh or arm of the subject and is passed through the blood vessels to the desired site in the cardiovascular system. Once the guide wire has reached the desired site, the catheter is then advanced over the guide wire to the site. Guide wires are also extensively used to guide a catheter to other sites in the venal system, and also to sites in the renal system, as well as to other sites in human and animal subjects through other accessing systems.

Due to the relatively narrow diameter of the blood vessels through which the guide wire has to pass, and in particular, due to the tortuous nature of the blood vessels of the cardiovascular and other venal systems, and the number of branching blood vessels, it is essential that the guide wire be of a construction which facilitates bending of the guide wire so that the guide wire can be bent around corners, and

can be directed into a desired one of branching blood vessels. Various attempts have been made to provide such guide wires, for example, such a guide wire is described in U.S. Patent Specification No. 4,545,390 of Leary and U.S. Patent Specification No. 4,080,706 of Heilman, et al. While the guide wires described in these two prior art specifications are flexible and suitable for bending around corners of the blood vessels of the venal system, they suffer from a disadvantage in that it is difficult to initially direct the guide wire around the corner, and in particular, it is difficult to direct the guide wire from one blood vessel into a branching blood vessel. In order to overcome this problem, the distal portion of known guide wires are shaped for facilitating bending of the distal portion to form a curved distal portion, which can then be directed towards a branching blood vessel into which the guide wire is to be directed, and also for facilitating aligning the guide wire with a corner or bend in a vessel of the venal, renal or any other system.

However, in general, the distal portions of such guide wires which are adapted for facilitating the formation of a curvature for in turn facilitating guiding the guide wire into branching vessels of a venal, renal or other system tend to buckle in the plane in which the curvature is formed while the guide wire is being urged through the venal, renal or other system of the subject. Such buckling commonly occurs when the guide wire is being urged around a bend or into a branching vessel. This is undesirable, since the buckling of the distal portion of the guide wire renders it difficult to urge the guide wire through the venal or renal system.

There is therefore a need for a guide wire for use in a surgical or other procedure for

accessing a remote site in the body of a human or animal subject which is also suitable for use with a catheter and which overcomes this problem.

The present invention is directed towards providing such a guide wire, and the invention is also directed towards providing a method for producing a guide wire which overcomes the problems of prior art guide wires.

According to the invention, there is provided an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, the guide wire defining a longitudinally extending axis, and extending axially between a distal end for accessing the remote site, and a spaced apart proximal end, a distal portion of the guide wire adjacent the distal end thereof being shaped into a curvature configuration for facilitating guiding of the guide wire around a bend, wherein the distal portion is of substantially rectangular cross-section defining a pair of spaced apart major surfaces, and a pair of spaced apart minor surfaces extending between the major surfaces, the distal portion further defining a major plane extending intermediate the major surfaces and bisecting the minor surfaces, and a minor plane extending intermediate the minor surfaces and bisecting the major surfaces, the distal portion being curved in the major plane.

In one embodiment of the invention, the major surfaces of the distal portion converge towards the distal end.

In another embodiment of the invention, the minor surfaces of the distal portion

diverge towards the distal end.

In one embodiment of the invention, the distal portion of the guide wire is of a material and dimensions which retain the curvature formed therein.

In another embodiment of the invention, the distal portion is of a material and dimensions for facilitating subsequent formation of a curvature therein in the minor plane thereof.

In one embodiment of the invention, the distal portion is integrally formed with the guide wire. Alternatively, the distal portion is formed separately of the guide wire and is secured thereto.

In one embodiment of the invention, the distal portion of the guide wire terminates in a bulbous portion for facilitating guiding of the guide wire through the venal, renal or other systems without damaging vessels of the venal, renal or other systems.

In another embodiment of the invention, the bulbous portion is radiused, and ideally terminates in a leading end which is partially spherical.

In another embodiment of the invention, a sleeve is provided around the guide wire adjacent the distal end, and preferably, the sleeve extends from the bulbous portion of the guide wire, and ideally, extends away from the distal end along the guide wire beyond the distal portion, and ideally, terminates at a location intermediate the distal

portion and the proximal end, and preferably, is secured to the guide wire, and ideally, is secured by brazing.

In a further embodiment of the invention, the sleeve is of a radiopaque material, and in another embodiment of the invention, the sleeve terminates in a portion of radiopaque material.

In one embodiment of the invention, the radiopaque material of the sleeve is selected from one or more of the following:

platinum,

platinum alloy,

gold,

tantalum.

In another embodiment of the invention, the sleeve comprises a tightly coiled spring, and in a further embodiment of the invention, the sleeve is of a plastics material, in a still further embodiment of the invention, the sleeve is of a plastics material and a metal material.

The invention also provides in combination the guide wire according to the invention and a catheter.

Additionally, the invention provides a method for forming a curvature on a distal

portion of a guide wire for facilitating urging of the guide wire through the body of a human or animal subject during a surgical or other procedure, the method comprising the steps of:

providing the distal portion of the guide wire of substantially rectangular cross-section defining a pair of spaced apart major surfaces, and a pair of spaced apart minor surfaces extending between the major surfaces, the distal portion further defining a major plane extending intermediate the major surfaces and bisecting the minor surfaces, and a minor plane extending intermediate the minor surfaces and bisecting the major surfaces, and

forming the distal portion with a curvature configuration in the major plane for facilitating guiding the guide wire around a bend.

Preferably, the distal portion is provided with the major surfaces converging towards a distal end, and ideally, the minor surfaces diverging towards the distal end.

Ideally, the dimensions of the distal portion are selected so that the distal portion retains the curvature formed therein.

Preferably, the material of the distal portion is provided for retaining the curvature formed therein.

Ideally, the material and the dimensions of the distal portion of the guide wire are selected for facilitating subsequent forming of a curvature therein in the minor plane thereof.

In one embodiment of the invention the curvature is formed in the distal portion prior to the formation of the distal portion of substantially rectangular cross-section.

Additionally, the material and the dimensions of the distal portion are selected to prevent buckling thereof, in use.

The invention will be more clearly understood from the following description of an embodiment thereof which is given by way of example only with reference to the accompanying drawings in which:

Fig. 1 is a partly cut-away side elevational view of a guide wire according to the invention for use with a catheter,

Fig. 2 is a partly cutaway plan view of the guide wire of Fig. 1,

Fig. 3 is an enlarged view of a portion of the guide wire of Fig. 1,

Fig. 4 is a perspective view of a portion of the guide wire of Fig. 1,

Fig. 5 is a plan view of the portion of the guide wire of Fig. 4,

Fig. 6 is a side elevational view of the portion of the guide wire of Fig. 4,

Fig. 7 is an end elevational view of the portion of the guide wire of Fig. 4,

Fig. 8 is a perspective view of a portion of a guide wire according to another embodiment of the invention,

Fig. 9 is a plan view of the portion of the guide wire of Fig. 8, and

Fig. 10 is a perspective view of a portion of a guide wire according to another embodiment of the invention.

Referring to the drawings, and initially to Figs. 1 to 7 thereof, there is illustrated a guide wire according to the invention indicated generally by the reference numeral 1 for use with a catheter (not shown) for guiding the catheter to a remote site in the body of a human or animal subject. The guide wire according to this embodiment of the invention is particularly suitable for accessing a remote site in the cardiovascular system of a subject for in turn guiding the catheter (not shown) to the remote site. Although, it will be readily apparent to those skilled in the art that the guide wire 1 is also suitable for accessing any remote site in the body of a human or animal subject, be it in a vascular system or otherwise. For example, the guide wire 1 is suitable for accessing a renal system, the neuro-vascular system, the fallopian tubes and other such vessels and sites.

The guide wire 1 comprises an elongated wire core 2 which in this embodiment of the invention is of stainless steel, and which defines a longitudinally extending axis 4

and extends from a proximal end 5 to a distal end 6. The distal end 6 of the wire core 2 terminates in a bulbous portion 8 of stainless steel, which terminates in a spherical leading end for facilitating guiding of the guide wire through the vascular system of the subject and for avoiding scarring, rupturing or otherwise damaging the vessels of the vascular system through which the guide wire 1 is being urged. A sleeve 9, in this embodiment of the invention formed by a tightly wound coiled spring of radiopaque material, namely, platinum alloy material, extends from the bulbous portion 8 away from the distal end 6 and terminates at a location 10 on the wire core 2. The sleeve 9 is secured by brazing to the bulbous portion 8 and the wire core 2.

In this embodiment of the invention, the wire core 2 is of circular transverse cross-section, and tapers in three stages 11, 12 and 13 to a portion 15 of reduced circular cross-section. A distal portion 16 of the wire core 2 extends from the portion 15 to the bulbous portion 8, and is of rectangular cross-section defining a pair of major surfaces 18 and 19 which are joined by a pair of minor surfaces 20 and 21. The major surfaces 18 and 19 converge from the portion 15 to the bulbous portion 8, while the minor surfaces 20 and 21 diverge from the portion 15 to the bulbous portion 8. The distal portion 16 also defines a major plane 24 which extends intermediate the major surfaces 18 and 19 and bisects the minor surfaces 20 and 21. A minor plane 25 extends intermediate the minor surfaces 20 and 21 and bisects the respective major surfaces 18 and 19. The distal portion 16 is pre-curved in the major plane 24 for facilitating guiding the guide wire 1 into branching vessels of the vascular system of the subject.

In this embodiment of the invention, the distal portion 16 is of stainless steel and is formed from the same piece of stainless steel from which the wire core 2 is formed.

The wire core 2 with the distal portion 16 is formed as follows. Initially, the wire core 2 is shaped to form the tapering stages 11, 12 and 13. The distal portion 16 is initially formed to be of diameter similar to that of the portion 15. The desired curvature is then formed in the portion 15 which will ultimately form the distal portion 16, and the curved portion of the portion 15 is then shaped to define the rectangular cross-section with the major surfaces 18 and 19 converging towards the distal end 6 and the minor surfaces 20 and 21 diverging towards the distal end 6, thereby forming the distal portion 16. After completion of the formation of the distal portion 16, the bulbous portion 8 is then brazed onto the distal portion 16. The curvature may be formed by any suitable means, for example, bending the portion 15 which is to form the distal portion 16 around a suitably shaped jig, and then forming the distal portion of the rectangular cross-section in a press tool or cam rollers. Alternatively, the distal portion 16 may be formed separately from the wire core 2, by, for example, cutting an appropriately curved ribbon from flat stock, and using a laser, press tool or electrochemical etch for forming the rectangular shaping of the distal portion 16. The so formed distal portion 16 would then be brazed to the wire core 2, and the bulbous portion 8 would in turn be brazed to the distal portion 16. Alternatively, offset rollers may be employed to create the taper and curvature in one single press where the distal portion 16 is formed integrally with the wire core 2.

Prior to brazing the bulbous portion 8 to the distal portion 16, the sleeve 9 is

threaded onto the distal portion 16 and the wire core 2 and then after brazing of the bulbous portion 8 to the distal portion 16, the sleeve is then brazed to the bulbous portion 8 and to the wire core 2 at the location 10.

It is envisaged that a set of guide wires will be provided with respective different curvatures to suit different applications. The guide wire 1 illustrated in Figs. 1 and 2 is provided with a 90° curvature.

Additionally, the material and dimensioning of the distal portion 16 is such as to permit subsequent manual bending of the distal portion in the minor plane, so that two degrees of curvature can be achieved, namely, the curvature of the distal portion in the major plane, and the curvature of the distal portion in the minor plane.

In use, depending on the vascular system of the subject to be accessed, a guide wire 1 with the distal portion 16 of the appropriate curvature in the major plane 24 is selected. If appropriate, a further curve is manually induced in the distal portion 16 in the minor plane 25. The guide wire 1 is then ready for use and is used thereafter in conventional fashion.

The advantages of the invention are many. Firstly, the fact that the curvature of the distal portion is formed in the major plane avoids any danger of buckling of the guide wire as it is being urged through the vascular system in the major plane. Furthermore, by virtue of the fact that the distal portion 16 is pre-curved in the major plane, the rectangular cross-section of the distal portion may be such as to provide

the distal portion to be more rigid than distal portions of guide wires known heretofore, and thereby avoiding buckling of the distal portion as the guide wire is being urged through the vascular system. Furthermore, the guide wire of the present invention facilitates imposing curvature in the distal portion in two planes, which further facilitates and assists in guiding the guide wire as it is being urged through the vascular system of the subject. Indeed, the effect of forming curvatures in both the major and minor planes of the distal portion provides the distal portion with a corkscrew or helical type effect.

Referring now to Figs. 8 and 9, there is illustrated a portion of a guide wire according to another embodiment of the invention indicated generally by the reference numeral 30. The guide wire 30 is substantially similar to the guide wire 1, and similar components are identified by the same reference numerals. The main difference between the guide wire 30 of Figs. 8 and 9 is that the bend formed in the distal portion 16 of the guide wire 30 is less acute than the bend formed in the distal portion 16 of the guide wire 1. Otherwise, the guide wire 30 is similar to the guide wire 1, and its use is likewise similar.

Referring now to Fig. 10, there is illustrated a portion of a guide wire according to a further embodiment of the invention, indicated generally by the reference numeral 40. The guide wire 40 is substantially similar to the guide wire 1 and similar components are identified by the same reference numerals. However, in this embodiment of the invention only half the distal portion 16 of the guide wire 40 is illustrated in Fig. 10. The distal portion 16 is bisected by the major plane 24. The

other half of the distal portion 16 is a mirror image of the illustrated portion.

The only difference between the guide wire 40 and the guide wire 1 is that in the guide wire 40, the distal portion 16 is provided with a reinforcing means provided by a pair of reinforcing plates 41 which extend on opposite sides from the major surfaces 18 and 19, respectively. The reinforcing plates 41 extend along the longitudinally extending axis 4 of the wire core 2 and lie in the minor plane 25 prior to bending of the distal portion 16. The reinforcing plates 41 may be formed integrally with the distal portion 16, or may be formed separately and welded or brazed to the distal portion 16. The advantage of providing the reinforcing plates 41 is that since the reinforcing plates 41 lie in the minor plane, they act to enhance the rigidity of the distal portion 16 against bending or buckling in the minor plane as the guide wire is being urged through the vascular system of the subject. Indeed, in general, it is envisaged that the reinforcing plates 41 will be of material and will be dimensioned for facilitating bending of the distal portion 16 in the minor plane so that the distal portion 16 will be bent in both the major and minor plane, the bend in the minor plane will be typically formed adjacent the distal end 6 to provide the distal portion 16 with a type of corkscrew action. Typically, it is envisaged that the bending of the distal portion 16 in the minor plane would be carried out manually prior to use of the device, although it will be appreciated that bending of the distal portion in the minor plane could be factory carried out while the distal portion is being bent in the major plane.

While the wire core, the distal portion, the bulbous portion and the sleeve have been

described as being of specific materials, it is envisaged that the wire core, the distal portion, the bulbous portion and the sleeve may be of any other desired or suitable materials, and in certain cases, it is envisaged that the sleeve may be of plastics material, or portions of the sleeve may be of a plastics material.

It is also envisaged that instead of the sleeve being of radiopaque material, where it is desired to have a portion of the guide wire adjacent its distal end to be radiopaque, it is envisaged that the bulbous portion may be of a radiopaque material, for example, platinum alloy.

Needless to say, the distal portion may be of a radiopaque material.

While the distal portion has been described as being of rectangular transverse cross-section, the cross-section of the distal portion may not be exactly rectangular, for example, the minor surfaces may be convex.

While the bulbous portion at the distal end of the guide wire has been described as being of stainless steel, in certain cases, it is envisaged that the bulbous portion may be formed solely by solder or other metal resulting from soldering or brazing the sleeve to the wire core at the distal end 6.

The invention is not limited to the embodiment hereinbefore described, which may be varied in construction and detail.

F.F. GORMAN & CO.

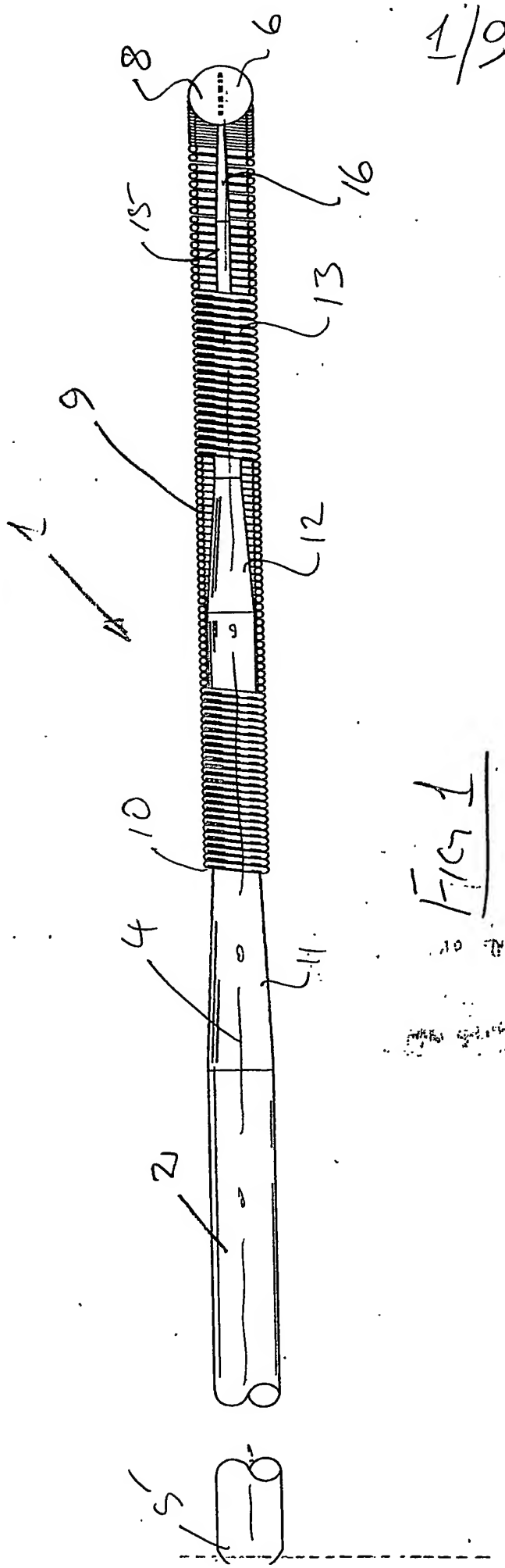

FIG 1

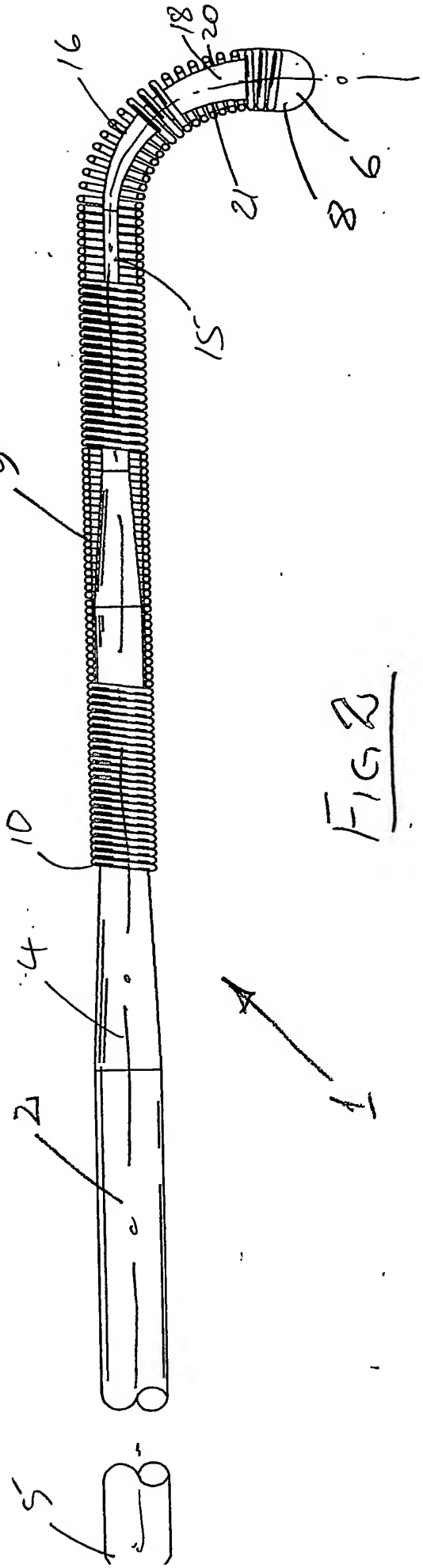

FIG 2

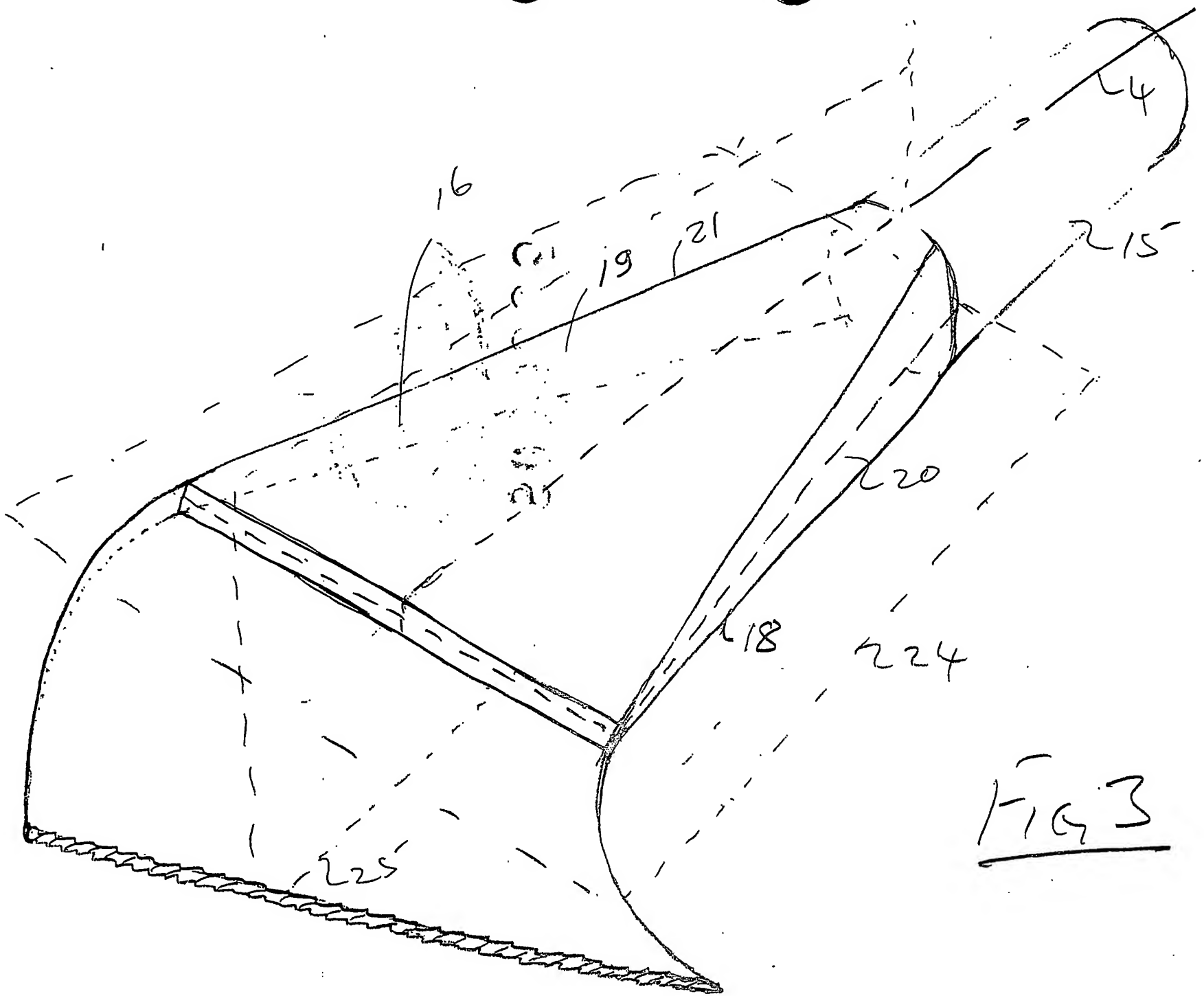

FIG 3

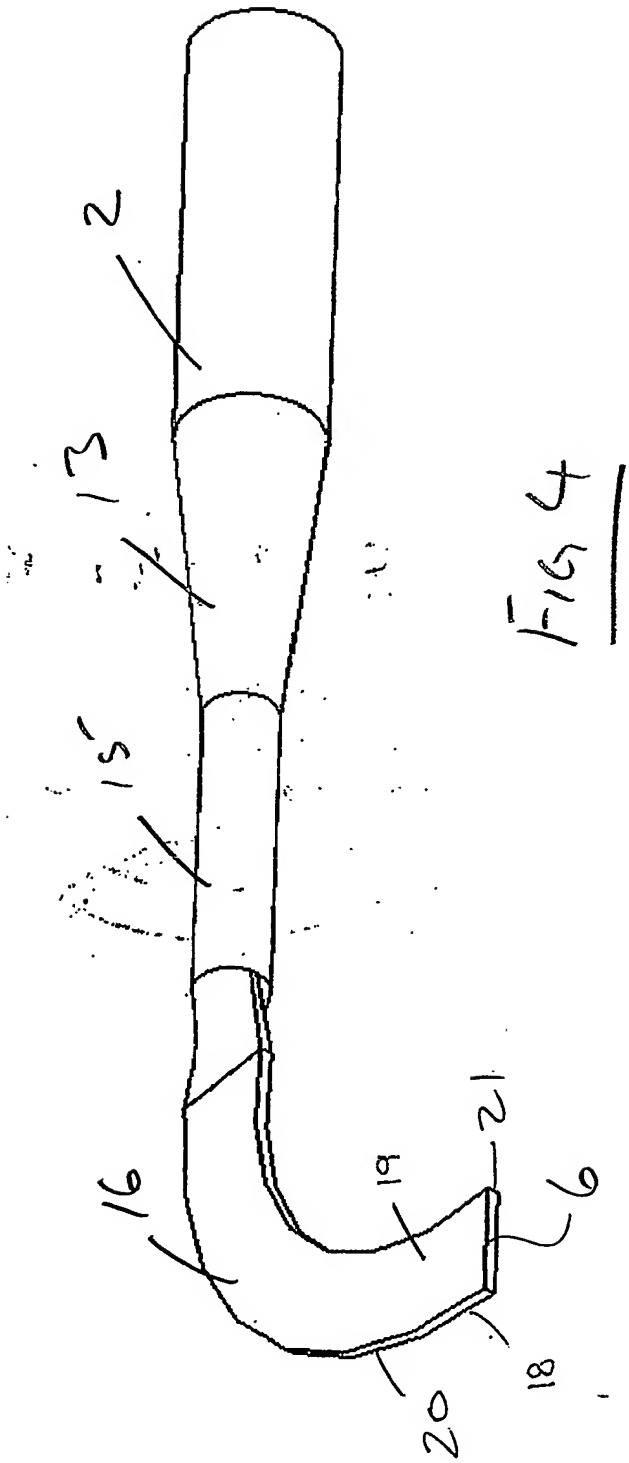

FIG 4

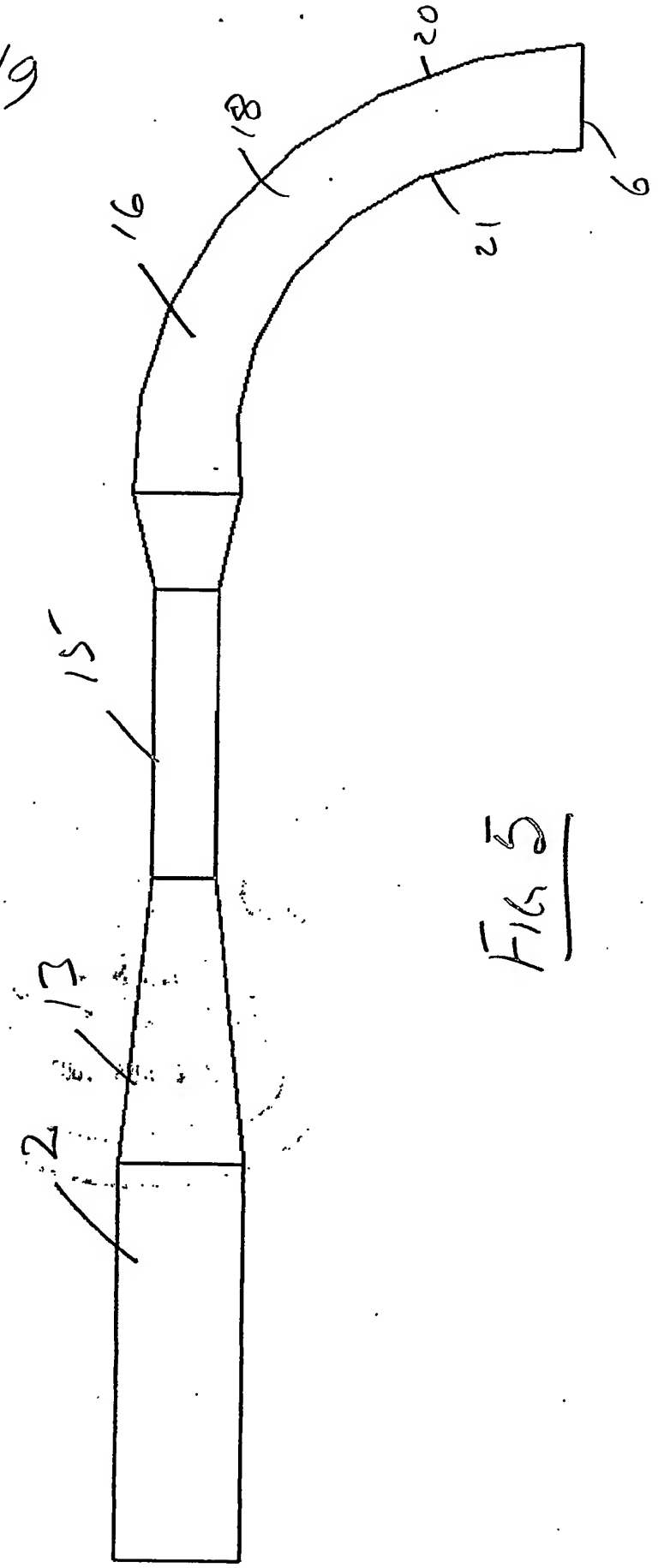

FIG 5

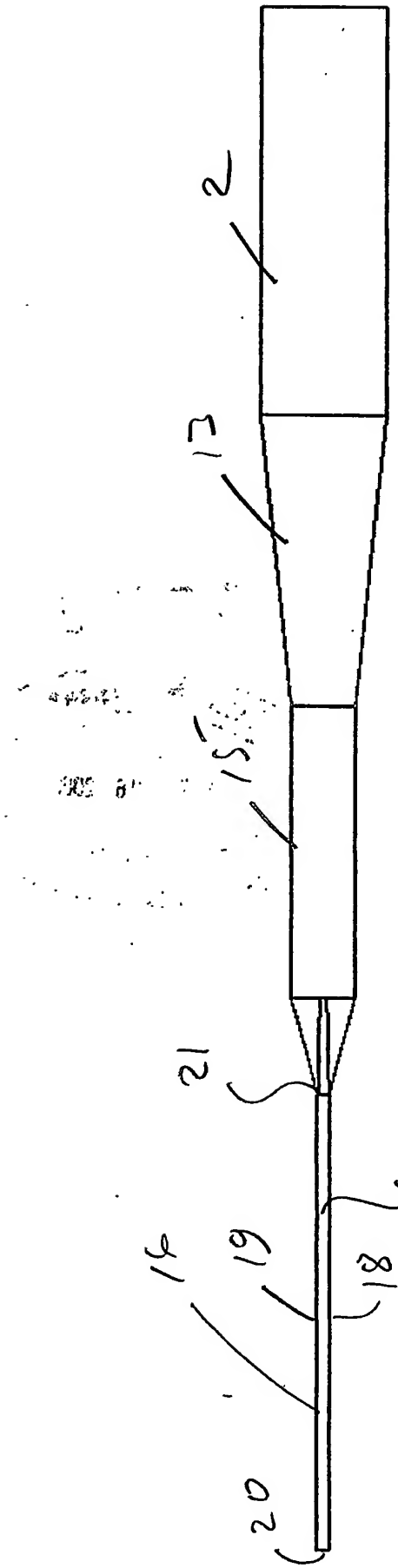

FIG 6

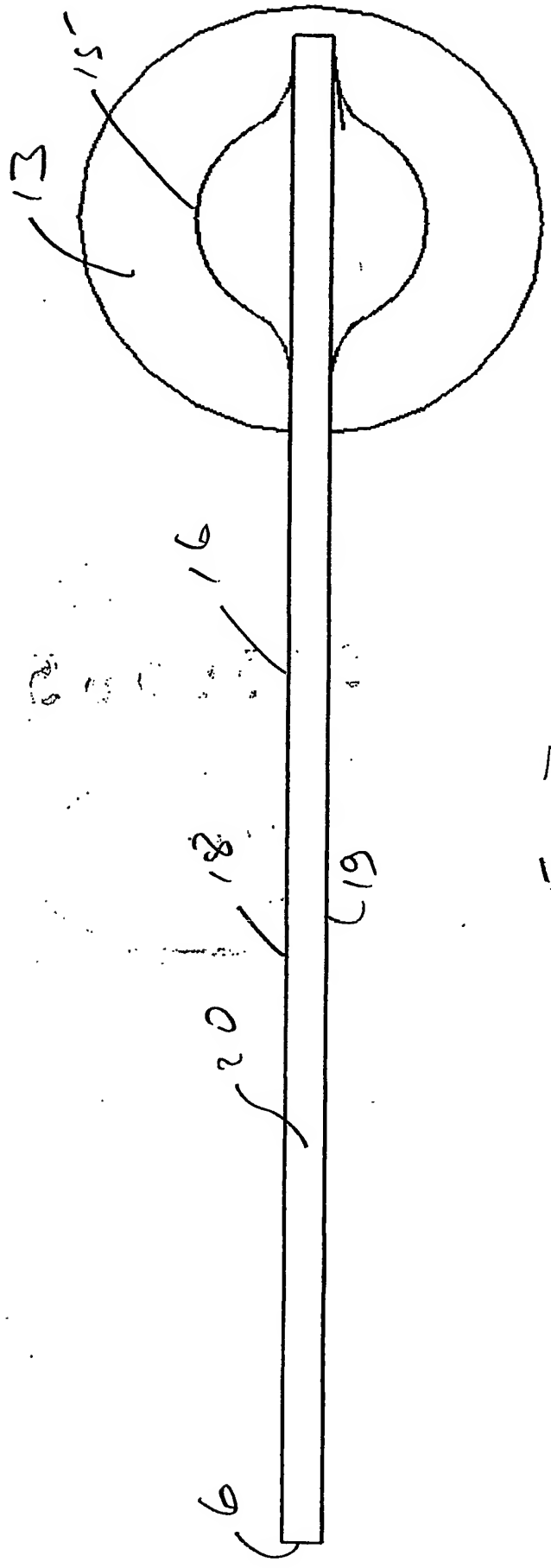

Fig 7

FIG 8

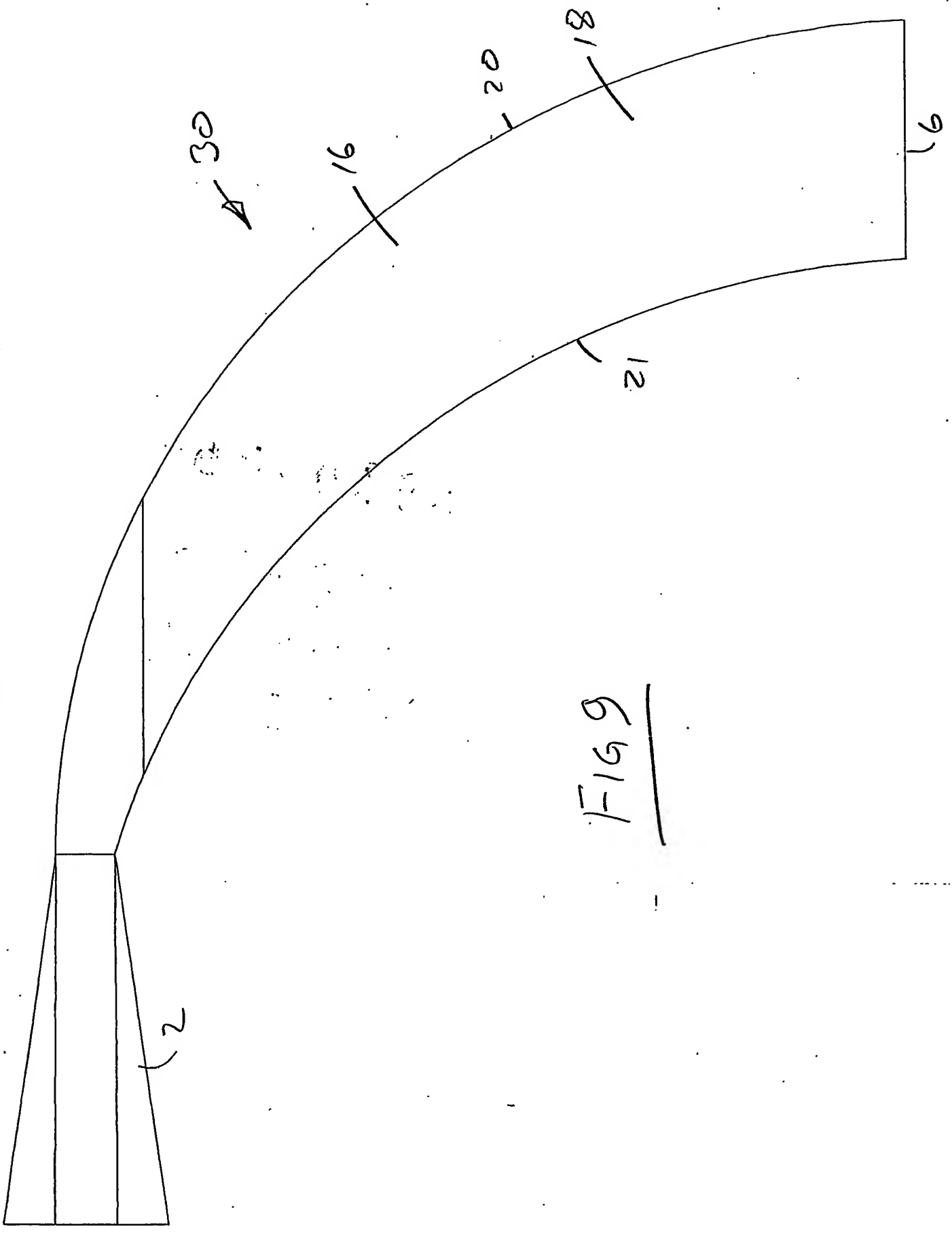

Fig 9

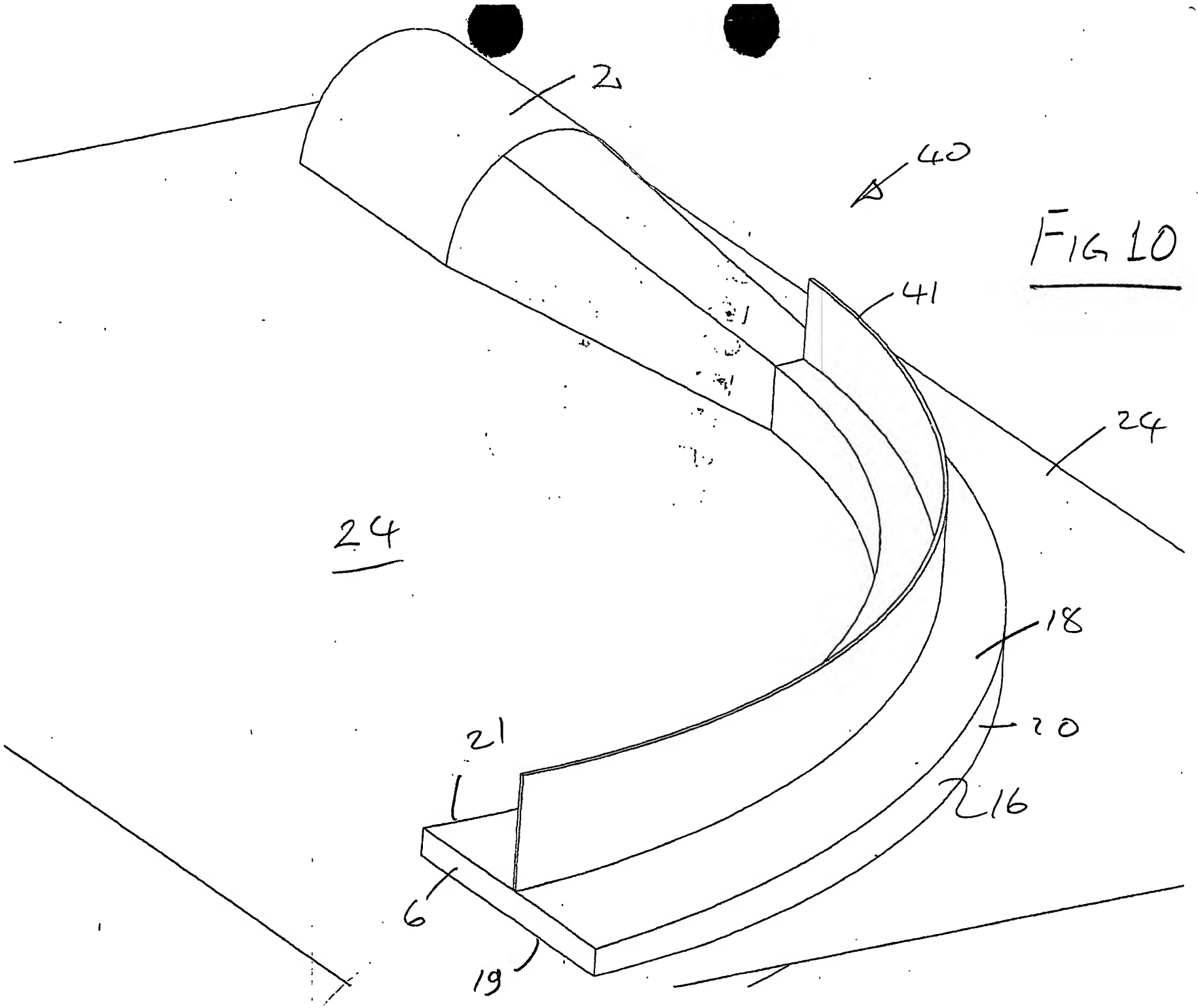

FIG 10